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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/833,222	QIN ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims:

Applicants' communication of 25 May 2007 (in response to Office Action of 27 December 2007) made of record.

Claims 1-5, 7 and 13 have been amended and the amendment made of record.

Claims 1-5, 7, and 13 are under consideration.

Withdrawn Objections/Rejections

Objections:

The objection to Claims 5 and 13 because of misspellings is withdrawn. Applicant has corrected the errors.

Rejections:

The rejection of Claim 7 under 35 U.S.C. 101 is withdrawn in view of applicant's amendment to the claim.

The rejection of Claims 1-3, 5 and 13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim.

The rejection of claim 7 under 35 U.S.C. 112, first paragraph because the specification, while being enabling for an isolated or cultured host cell comprising an expression vector, does not reasonably provide enablement for any generic host cell comprising an expression vector is withdrawn in view of applicants amendment to the claim.

The rejection of claims 1-3, 5, 7 and 13 under 35 U.S.C. 102 (b) as being anticipated by Klugbauer et al (1999. Jnl of Neuroscience 19:684-691) is withdrawn in view of applicant's amendment to the claims.

Maintained/New Rejections

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, and 13 are vague and indefinite in reciting an "α2δ-4 calcium channel". While the name itself may have convey some notion of the activity of the protein, there is nothing in the claim that distinctly identifies the protein, nor is the term defined in the specification. Applicant should particularly point out definitive characteristics associated with the protein. It is not clear to the examiner how the specific "α2δ-4 calcium channel subunit protein" differs from similar, regulatory calcium channel subunits. Thus "α2δ-4 calcium channel" is not sufficient to identify the claimed invention; one of skill in the art would not be able to determine the metes and bounds of the claim.

Claims 1 (a), 5 and 13 are vague and indefinite in reciting "a polypeptide having **a** sequence of SEQ ID NO:10". This phrase may encompass a polypeptide that comprises SEQ ID NO:10 or any portion thereof. Thus, it is unclear if applicant intends the full-length sequence of SEQ ID NO:10 or a fragment thereof. It is suggested that claims be amended to read, for example, "a polypeptide having **the** sequence....".

Claim 4 is vague and indefinite in reciting "having **a** nucleotide sequence of SEQ ID NO:9". This encompasses nucleic acids that comprise the full length sequence of SEQ ID NO:9 or any portion of SEQ ID NO:9. Thus, it is unclear if the claim is directed to the full length sequence or any sequence of two or more nucleotides fully contained with SEQ ID NO:9. It is suggested that the claim be amended to read, for example, "a nucleic acid molecule having **the** nucleotide sequence....".

Claims 2, 3, and 7 are included in this rejection as dependent from rejected claims.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 1 and 4 recite 'An isolated and purified nucleic acid molecule encoding an α2δ-4 calcium channel subunit protein.....comprising (a) a polynucleotide encoding a polypeptide having **a** sequence.....; (b) a nucleic acid molecule that is complementary to polynucleotide of (a); (c) a nucleic acid molecule that hybridizes.....to the polynucleotide of (a).....; (d) a nucleic acid molecule that encodes a splice variant of a human α2δ-4 calcium channel subunit comprising exon 1B; (e) a nucleic acid molecule that encodes a splice variant of a human α2δ-4 calcium channel subunit comprising exon 37B; and (f) a human α2δ-4 calcium channel subunit comprising exon 37B (claim 1) and "An isolated and purified nucleic acid molecule having a nucleotide sequence of SEQ ID NO:9" (Claim 4).

The claims do not identify any particular biological activity that must be retained in order that the polypeptide be identifiable as an α2δ-4 calcium channel subunit nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that are defined only a being an α2δ-4 calcium channel subunit or being hybridizable to a polynucleotide encoding a polypeptide of SEQ ID NO:10.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product or any combination thereof. In this case, the only factor present in the claim is a partial structure (claim 1 a and b), recitation of hybridization ability (claim 1c) or a protein comprising 1 or 2 specified exons (claims 1 d-f). The preamble of claim 1 identifies the molecule as encoding an α2δ-4 calcium channel subunit, but does not recite any characteristics that would distinguish this particular calcium channel subunit from other α2δ subunits. The art recognizes, that even under stringent hybridization conditions, mismatches will occur. Thus, for example, a nucleic acid encoding an α2δ-D subunit which is 94.1% identical to the α2δ-4 calcium channel subunit of the instant invention (Johns et al. 2000. WO 200020450, SEQ ID NO:4, see below) would be expected to hybridize to the nucleic acid of the instant invention. The claim recites a nucleic acid encoding a splice variant comprising one or two specific exons, but does not specify what other exons the nucleic acid must comprise in order to encode an α2δ-4 calcium channel subunit. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide written description of the claimed genus.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus.

There are only 2 species of the claimed genus, the polynucleotide of SEQ ID NO:9 composed of 36 invariant exons (exon2-exon 36) and 4 alternative exons (exon 1, 1A, 37 and 37B) and an a polynucleotide comprising exon 1B and exons 2-37 disclosed that is within the scope of the claimed genus, *i.e.* α2δ-4 calcium channel subunit (page 69, Example 3). The disclosure of 2 species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is α2δ-4d calcium channel subunit. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. Therefore, only isolated polynucleotides comprising SEQ ID NO:9 or a nucleic acid comprising exon 1B and exons 2-37 but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Johns et al. (2000. WO 00/20450). As stated above, the language of the claims, reciting "a polynucleotide encoding a polypeptide having a sequence of SEQ ID NO:10" and "nucleic acid molecule having a nucleotide sequence of SEQ ID NO:9" is interpreted to mean a polynucleotide encoding a polypeptide that comprises the full length sequence of SEQ ID NO:10 or any portion of SEQ ID NO:10, or a nucleic acid that comprises full length of SEQ ID NO:9 or any portion of SEQ ID NO:9, including any dinucleotide or larger oligonucleotide.

Johns et al teach an alpha-2 delta D gene, which is a subunit of many calcium channels (abstract). SEQ ID NO:4 is 88.5% identical to the sequence of SEQ ID NO:9; this nucleic acid sequence encodes the polypeptide of SEQ ID NO:6 which is 94.1% identical to SEQ ID NO:10 of the instant invention (see enclose alignment). Residues 225-2634 of SEQ ID NO:9 are identical to residues 179-2594 of SEQ ID NO:4, residues 2636-3307 of SEQ ID NO:9 are identical to residues 2596-3261 of SEQ ID NO:4. Amino acid residues 60-632, 634-861 and 863-1086 of SEQ ID NO:6 are identical to amino acid residues 13-585, 587-814 and 816-1039, respectively of SEQ ID NO:10, the encoded polypeptide of the instant invention. As noted above, "α2δ-4" is not defined, in the claims or in the specification; thus the term is given minimal patentable weight. Absent evidence to the contrary, SEQ ID NO:4 taught by Johns et al. would hybridize under stringent conditions to SEQ ID NO:9, of the instant invention, thus meeting the limitations of Claim 1. Furthermore, SEQ ID NO:4, encoding the polypeptide of SEQ ID NO:6 meets the definition of a nucleic acid molecule encoding a polypeptide having **a** sequence of SEQ ID NO:10 (claim 1) and having **a** nucleotide sequence of SEQ ID NO:9 (Claim 4). As stated above, a "polynucleotide encoding a polypeptide having a sequence of SEQ ID NO:10" is interpreted as a polynucleotide encoding a polypeptide that comprises any portion of SEQ ID NO:10; a "nucleic acid molecule having a nucleotide sequence of SEQ ID NO:9" is interpreted as a polynucleotide that comprises

any portion of SEQ ID NO:9, including any dinucleotide or larger oligonucleotide. The reference teaches polynucleotides may be DNA or RNA molecules (page 13) lines 5-10), thereby meeting the limitations of claims 2 and 3. Johns et al. teach expression vectors (page 16, lines 1-3), host cells (page 16 line 29) and the use of host cells to recombinantly produce the alpha-2 delta D protein (page 16, line 28-page 17, line 13), thereby meeting the limitations of claims 5, 7 and 13. Thus, the teachings of Johns et al anticipate all the limitations of claims 1-5, 7 and 13.

Conclusion:

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHS

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